IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS DALLAS DIVISION

UNITED STATES OF AMERICA ET AL. ex rel. RAYBURN ALEX THOMPSON,

Plaintiffs

v.

Civil Action No. 3:20-cv-2917-D

APOLLO PATH, LLC D/B/A APOLLO LABORATORIES; APOLLO LABORATORIES SERVICES, LLC; ARBOR DIAGNOSTICS, INC.; KORENVAES MANAGEMENT, LLC; DAVID KEY; BRIAN OLIVER; and MAX KORENVAES

Defendants.

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

AKIN GUMP STRAUSS HAUER & FELD LLP Elizabeth D. Scott 2300 North Field Street Suite 1800 Dallas, TX 75201 AKIN GUMP STRAUSS HAUER & FELD LLP
Robert Salcido
Emily Gerry
Robert S. Strauss Tower
2001 K Street N.W.
Washington, DC 20006

TABLE OF CONTENTS

				Page	
I.	BAC	BACKGROUND			
II.	THE	THE COURT SHOULD DISMISS RELATOR'S CLAIMS			
	A.	The	The Court Should Dismiss Relator's Action Under Rule 12(b)(6)		
		1.	Relator's FAC Does Not Plausibly Plead FCA Falsity	2	
		2.	Relator's FAC Does Not Plausibly Plead Causation	5	
		3.	Relator Does Not Plausibly Plead that Defendants Acted with the Requisite Scienter	6	
		4.	Relator Does Not Plausibly Plead FCA Conspiracy	7	
	B.	Relator's FCA Allegations Fail to Meet Rule 9(b)'s Heightened Pleading Requirements		9	
III.	CONCLUSION			10	

TABLE OF AUTHORITIES

Page(s)
Cases
Ashcroft v. Iqbal, 556 U.S. 662 (2009)
Bingham v. HCA, Inc., 783 F. App'x 868 (11th Cir. 2019)
<i>GF Indus. of Mo., LLC v. Lehigh Valley Genomics, LLC</i> , 2024 U.S. Dist. LEXIS 78245 (E.D. Pa. Apr. 30, 2024)
<i>H&B Equip. Co. v. Int'l Harvester Co.</i> , 577 F.2d 239 (5th Cir. 1978)9
Hawaii ex rel. Torricer v. Liberty Dialysis-Hawaii LLC, 512 F. Supp. 3d 1096 (D. Haw. 2021)8
S&G Labs Haw., Ltd. Liab. Co. v. Graves, 2021 U.S. Dist. LEXIS 200365 (D. Haw. Oct. 18, 2021)2, 7
U.S. ex rel. Cairns v. D.S. Med. LLC, 42 F.4th 828 (8th Cir. 2022)
U.S. ex rel. Colquitt v. Abbott Labs., 858 F.3d 365 (5th Cir. 2017)
<i>U.S. ex rel. DRC, Inc. v. Custer Battles, LLC,</i> 376 F. Supp. 2d 617 (E.D. Va. 2005), rev'd in part on other grounds, 562 F.3d 295 (4th Cir. 2009)
U.S. ex rel. Hanna v. City of Chi., 834 F.3d 775 (7th Cir. 2016)9
U.S. ex rel. Hart v. McKesson Corp., 96 F.4th 145 (2d Cir. 2024)
U.S. ex rel. Head v. Kane & Co., 798 F. Supp. 2d 186 (D.D.C. 2011)8
U.S. ex rel. Integra Med Analytics, LLC v. Baylor Scott & White Health, 816 F. App'x 892 (5th Cir. 2020)
<i>U.S. ex rel. Martin v. Hathaway</i> , 63 F.4th 1043 (6th Cir. 2023)

U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451 (4th Cir. 2013)	.9
U.S. ex rel. Nicholson v. MedCom Carolinas, Inc., 42 F.4th 185 (4th Cir. 2022)1	1
U.S. ex rel. Rector v. Bon Secours Richmond Health Corp., 2014 U.S. Dist. LEXIS 52161 (E.D. Va., Apr. 14, 2014)	.8
United States v. Marchetti, 96 F.4th 818 (5th Cir. 2024)	m
United States v. Medoc Health Servs., LLC, 470 F. Supp. 3d 638 (N.D. Tex. 2020)	.8
United States v. Miles, 360 F.3d 472 (5th Cir. 2004)	m
United States v. Omnicare, 663 F. App'x 368 (5th Cir. 2016)	.7
United States v. Shoemaker, 746 F.3d 614 (5th Cir. 2014)	.5
Wade v. Jackson Ass'n of Realtors, 615 F. App'x 238 (5th Cir. 2015)	.8
Statutes	
31 U.S.C. § 3729(b)	.7
2 U.S.C. § 1320a-7b(b)	.3
Other Authorities	
Rule 9(b)2, 9, 1	0
Rule 12(b)(6)	.2

I. BACKGROUND

As Relator concedes, under binding Fifth Circuit authority, to plausibly plead a potential violation of the Anti-Kickback Statute ("AKS"), Relator must plausibly plead the following: "[m]edical service provider pays salesman, salesman makes choice about service provider, salesman is never overruled." ECF 58 at 25 (quoting *United States v. Marchetti*, 96 F.4th 818, 831 (5th Cir. 2024)). This is because merely alleging that a salesperson is compensated under a percentage-based compensation structure is insufficient to allege an AKS violation; instead, under Fifth Circuit precedent, "something more" must be alleged—that is, that the salesperson intended to improperly influence those who make healthcare decisions on behalf of patients. *Marchetti*, 96 F.4th at 827 (rejecting the government's position that percentage-based payment to sales representatives were sufficient to violate AKS because "it needed to prove [defendants] intended 'improperly [to] influence[]' . . . those who make healthcare decisions on behalf of patients" (internal citation omitted) (quoting *United States v. Miles*, 360 F.3d 472, 481 (5th Cir. 2004))).

That is precisely what Relator admits in his First Amended Complaint ("FAC") that he cannot do because neither he nor Defendants know what, if any, relationship existed between sales representatives and the gatekeeper clinicians who make healthcare decisions on behalf of patients. ECF 52 ¶ 159 ("Neither the Defendant entities nor their agents monitored or questioned the nature of any agreements between healthcare service providers and sales reps. As a result, they were unaware of any kickback arrangements between ALS sales reps with healthcare providers or their staff"). That is, Relator can plead no facts regarding what relationship any salesperson had with any medical practice that resulted in a decision by any clinicians—the gatekeepers—to refer any claim. In this sense, the salesperson's relationship to the clinician and patient is simply a black box to Relator, to Defendants, and to the Court. But this relationship is precisely the "something more" that must be alleged. *Marchetti*, 96 F.4th at 827. Because Relator cannot populate this

PageID 446

black box with plausible facts setting forth any salesperson's improper influence over any clinician's professional judgment, he cannot plead plausible claims under Rule 12(b)(6) or with the specificity required by Rule 9(b). Hence, his FAC should be dismissed with prejudice.

II. THE COURT SHOULD DISMISS RELATOR'S CLAIMS

Case 3:20-cv-02917-D

A. The Court Should Dismiss Relator's Action Under Rule 12(b)(6)

1. Relator's FAC Does Not Plausibly Plead FCA Falsity

Relator does not plausibly plead FCA falsity because he does not allege that Defendants made any payment to any healthcare provider or patient, let alone that they paid sales representatives "remuneration," as defined by the only appellate court to rule on the issue. *See Bingham v. HCA, Inc.*, 783 F. App'x 868 (11th Cir. 2019). Additionally, Relator does not plead any plausible AKS violation because circuit precedent directly undermines his claim. *Marchetti*, 96 F.4th at 831.¹

Relator, not disputing that he never alleges that any Defendant made any payment to a medical provider, responds, first, that there is renumeration under the AKS because he alleges, in a conclusory fashion, that each Defendant paid or caused others to pay all sales representatives above fair market value ("FMV"). See ECF 58 at 9. But for purposes of Rule 12(b)(6), courts do not credit "a legal conclusion couched as a factual allegation" or a "naked assertion devoid of further factual enhancement." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Relator's assertion that all Defendants somehow caused all salespersons to be paid above FMV is merely a conclusory

¹ As to EKRA, Relator never attempts to distinguish court decisions expressly rejecting his theory that commissions paid to sales representatives based on their sales violates EKRA. These cases demonstrate that the type of compensation structure here is entirely *consistent* with EKRA, which is very far removed from a *knowing and willful violation* of EKRA. *See GF Indus. of Mo., LLC v. Lehigh Valley Genomics, LLC*, 2024 U.S. Dist. LEXIS 78245 (E.D. Pa. Apr. 30, 2024); *S&G Labs Haw., Ltd. Liab. Co. v. Graves*, 2021 U.S. Dist. LEXIS 200365 (D. Haw. Oct. 18, 2021).

statement devoid of any supporting facts and does not cure his failure to plead remuneration.

Second, Relator wrongly seeks to distinguish *Bingham* by contending that, here, the sales representatives' payments involved cash, while *Bingham* involved "non-cash" benefits. ECF 58 at 10. But in *Bingham*, the primary alleged "kickback" was, in fact, the payment of below-market rates for leases—an allegation the court rejected because the rates fell within FMV appraisals and thus could not be kickbacks. *See* 783 F. App'x at 870–71, 873–74. The distinction is nonsensical in any event because the AKS, on its face, applies to "remuneration" paid "in cash *or in kind*." 42 U.S.C. § 1320a-7b(b) (emphasis added). What mattered to the court was not whether the alleged kickback was cash or non-cash but whether payment was FMV or non-FMV. Because it was FMV, there was no AKS violation. Similarly, here, because Relator does not plausibly plead that anyone was paid above or below FMV, there is no AKS or EKRA violation as a matter of law.

Additionally, Relator's position here is directly contrary to the Fifth Circuit's decisions in *Marchetti* and *Miles. Marchetti* held that "it is legally correct to say that percentage-based compensation structures are not *per se* unlawful," and to prove a violation of law, the "structure of the contract alone is not sufficient evidence to produce a conviction under the [AKS]." 96 F.4th at 826, 831. Relator inexplicably seeks to distinguish *Marchetti* and *Miles* on the basis that he is alleging that Defendants paid all sales representatives on the basis of the *volume* of sales. *See* ECF 58 at 14–15. But in *Marchetti* and *Miles*, the sales representatives were also paid based on the volume of sales.² If Relator could plausibly plead that salespersons paid kickbacks to clinicians

Case 3:20-cv-02917-D

² In *Miles*, payment to a sales firm was directly based on volume. A home health agency ("HHA") paid the sales firm "\$300 for each Medicare patient" who became a patient of the HHA as a result of the firm's sales efforts. 360 F.3d at 479. The HHA's "payments to [the sales firm] were based on the number of Medicare patients that [HHA] secured from [the sales firm's] efforts." *Id.* at 480 (emphasis added). This volume-based payment did *not* result in an AKS violation because while the government would need to show that the relevant decisionmaker's

or otherwise exercised "improper influence"—that is, corrupted their clinical judgment regarding where their patients receive healthcare services—that would be a relevant distinction. But this is precisely what Relator admits that he *cannot* do. *See* ECF 52 ¶ 159. Accordingly, because the mere structure of a contract is insufficient to constitute a violation of these laws, and because Relator pleads nothing else, Relator fails to plead a plausible claim. *See Marchetti*, 96 F.4th at 831; *Miles*, 360 F.3d at 479–81; *see also Lehigh Valley Genomics*, *LLC*, 2024 U.S. Dist. LEXIS 78245, at *35–36 (applying these principles to EKRA).³

_

[&]quot;judgment was . . . improperly influenced," "[t]here was no evidence that [the sales firm] had any authority to act on behalf of a physician in *selecting* the particular home health care provider." *Id.* at 480–81. Similarly, in *Marchetti*, a lab paid an independent contractor sales group that had established relationships with physicians 35% of the business the lab received from the sales group. 96 F.4th at 821. Later, payment to the sales group may have evolved to "a percentage of 'net collected non-federal reimbursements' plus a fixed amount per month per 'active' representative." *Id.* at 822. Under either scenario, the payment the sales group received turned on the volume of business it secured for the lab. The court did not find this problematic under the AKS because the amount paid said nothing about whether a sales representative exercised improper influence over a doctor. *See id.* at 827. The court rejected the government's assertion that it was sufficient that salespersons had "relationships with, access to, and influence over" doctors and hence were paid to exercise that influence and use their connections, noting that "[p]lainly not every sort of influence is improper." *Id.*

Miles and Marchetti completely dispose of this action. Marchetti, 96 F.4th at 827; Miles, 360 F.3d at 479–81. A relator must allege "something more" than sales representatives having "relationships with, access to, and influence over" doctors and being paid on a volume basis—namely, that a person has "improper influence" over a doctor, something Relator admits he does not know. Marchetti, 96 F.4th at 827. It could be that physicians independently exercised their judgment as to which lab they would refer specimens based on what was best for their patients. Or, alternatively, in theory, it could be that physicians forfeited clinical judgment and let sales representatives decide what was best for their patients. But even crediting both scenarios as theoretically possible means that Relator's FAC should be dismissed because a "claim is merely conceivable and not plausible if the facts pleaded are consistent with both the claimed misconduct and a legal and obvious alternative explanation." U.S. ex rel. Integra Med Analytics, LLC v. Baylor Scott & White Health, 816 F. App'x 892, 897–99 (5th Cir. 2020). This is doubly true when, as here, Relator cannot assert in a non-conclusory fashion that a salesperson was paid anything but FMV for successful sales. And it is triply true when Relator cannot assert that any laboratory service was medically unnecessary or miscoded, resulting in an improper payment.

³ As to other Fifth Circuit case law, while Relator references *United States v. Cooper*, see ECF 58 at 13 n.9, he does not explain why this Court should prefer his definition of "referral" for

2. Relator's FAC Does Not Plausibly Plead Causation

Relator cannot plead "but-for" or any other type of causation. First, as to but-for causation, Relator misstates what Defendants must "cause" to establish liability. The focus is not on causing an alleged "kickback" (which here, of course, is non-existent for the reasons set forth above), but rather whether the kickback was the "but-for" cause for the referral—that is, whether false claims "resulted from" the alleged kickback. *See Martin*, 63 F.4th at 1052; *U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 834–35 (8th Cir. 2022). Here Relator does not plead any facts regarding any sales representative's interaction with any particular physician that would plausibly show that the salesperson's compensation structure *caused* the physician's referral of a claim to Apollo—as opposed to the *cause* of the referral simply being the physician's belief that Apollo provided the best testing service. Because Relator does not, and cannot, plead any facts as to what *caused* any physician to refer claims to Apollo, he cannot plead a plausible cause of action. *See Integra Med*

purposes of the AKS (i.e., a recommendation by a salesperson) to the Fifth Circuit's definition of "referral" in Cooper (i.e., "a doctor's recommendation of a provider" or "a doctor's authorization of care of a particular provider," 38 F.4th 428, 433 (5th Cir. 2022)). In the absence of plausibly pled, non-conclusory facts to the contrary (which are absent here), the presumption is that doctors refer the provider furnishing care to the patient. See id. at 433. Further, while Cooper applied the principle of lenity in an AKS criminal case, other circuits that have had occasion to consider its application in an AKS/FCA case have found that the principle of lenity applies because the same statutory language applies in both contexts. See U.S. ex rel. Martin v. Hathaway, 63 F.4th 1043, 1050 (6th Cir. 2023). As to Relator's use of United States v. Shoemaker, 746 F.3d 614 (5th Cir. 2014), see ECF 58 at 15, to minimize the need to show, consistent with Marchetti, that improper influence was exercised over a clinical decisionmaker, such a contention must be rejected because while "one might read Shoemaker for the proposition that Miles is not all about 'relevant decisionmakers'," that "would flatly contradict Miles," and, under Fifth Circuit precedent, "the earlier [case Miles,] . . . controls." Marchetti, 96 F.4th at 826 n.8. Miles is still good case law, as is Marchetti, which was decided only nine months ago. Indeed, the fact that Relator contends, in a conclusory fashion, that salespeople did not engage in a "marketing" role and "controlled" referrals demonstrates that he understands that if salespersons did market and did not have control over any physician's referrals, his action would be doomed under *Miles* and *Marchetti*. But, inconsistently, Relator admits that he cannot plead anything but a marketing role because he does not know how any salesperson interacted with any particular physician. See ECF 52 ¶ 159.

Analytics, LLC, 816 F. App'x at 897–99 (relator does not plead a plausible claim when facts are consistent with both the alleged misconduct and a legal and obvious alternative explanation).

Additionally, Relator does not plausibly plead that any particular Defendant undertook an affirmative action that caused an FCA violation. See ECF 55 at 11 (citing appliable case law). Relator asserts that he plausibly pleads FCA causation because various Defendants allegedly caused independent contractors to receive commissions to promote sales with medical providers. As this Circuit has pointed out, see Marchetti, 96 F.4th at 827; Miles, 360 F.3d at 479–81, this is lawful activity, and because it is lawful activity, it could not, by itself, cause the submission of false claims. See ECF 55 at 9 (citing cases). Instead, what could potentially "cause" false claims here, under the law, would be a salesperson exercising improper influence over a clinician to cause a referral to Apollo. But Relator does not plausibly plead that any Defendant took an affirmative action to cause a salesperson to exercise improper influence over a clinician for the simple reason that, as he admits, he has no knowledge of the interactions between the salespersons and clinicians (including whether they were "proper" or "improper"), and, as a result, he cannot plausibly plead FCA causation. See ECF 52 ¶ 159; see also Integra Med Analytics, 816 F. App'x at 897–99.

3. Relator Does Not Plausibly Plead that Defendants Acted with the Requisite Scienter

Relator applies the incorrect intent standard, which, once corrected, demonstrates that Relator does not plausibly plead the requisite intent. First, Relator wrongly applies the FCA's intent standard rather than the AKS's intent standard. *See* ECF 58 at 16–18. Relator's theory is that Defendants presented or caused to be presented "false" claims because those claims were tainted by AKS and EKRA violations. *See* ECF 52 ¶¶ 2–4. To establish, in the first instance, AKS and EKRA violations, Relator would need to plead that Defendants acted knowingly and willfully, the intent standard under both laws, which he does not do. *See, e.g., United States v. Omnicare*,

663 F. App'x 368, 373–74 (5th Cir. 2016) (relator must show underlying violation of AKS in FCA action); see also U.S. ex rel. Hart v. McKesson Corp., 96 F.4th 145, 155–57, 161 (2d Cir. 2024) (applying AKS scienter standard to assess whether relator plausibly pled FCA cause of action).⁴

Second, to have actionable scienter, Defendants must know that claims are false. *See* 31 U.S.C. § 3729(b). Relator misapplies this standard by asserting that he has pled sufficient scienter because he claims that Defendants knew that the compensation structure for salespersons was based upon volume and profitability of sales. *See* ECF 58 at 17–18. But, as this Circuit has explained, the "structure of the contract alone is not sufficient evidence to produce a conviction under the [AKS]." *Marchetti*, 96 F.4th at 826, 831. Defendants could not have known of any "false" claims in violation of the AKS by virtue of knowing the compensation structure for salespersons because that alone does not violate the AKS. Instead, the relevant question is whether any Defendant knew that any salesperson exercised improper influence over any particular doctor resulting in an unlawful referral to Apollo. But this is precisely what Relator admits that he cannot plead. *See* ECF 52 ¶ 159. Accordingly, Relator does not plausibly plead scienter.

4. Relator Does Not Plausibly Plead FCA Conspiracy

As to Relator's conspiracy count, Relator does not contest that if the Court finds that he cannot plausibly plead a substantive claim, his conspiracy claim should be dismissed, but only

_

⁴ Although there are numerous appellate court decisions under which Defendants' conduct is entirely lawful and appropriate—including because (i) no "remuneration" was paid under the AKS (*see Bingham*, 783 F. App'x at 873–74); (ii) there is no plausible allegation related to improper influence exercised over any particular clinician (*see Marchetti*, 96 F.4th at 831; *Miles*, 360 F.3d at 479–81); (iii) but-for causation was not and cannot be plausibly pled (*Martin*, 63 F.4th at 1052; *Cairns*, 42 F.4th at 834–35); and (iv) EKRA does not apply merely to paying commissions to independent contractor sales representatives (*see Lehigh Valley Genomics, LLC*, 2024 U.S. Dist. LEXIS 78245, at *35–36; *Graves*, 2021 U.S. Dist. LEXIS 20035, at *34)— Relator never explains how Defendants could *know* their conduct is *wrongful* when it is fully aligned with the undisputed body of appellate case law, including Fifth Circuit case law. *See* ECF 58 at 17–18.

asserts that he has plausibly pled such a claim. *See* ECF 58 at 21 n.11. Accordingly, if the Court concludes that Relator has failed to plead a plausible cause of action under the FCA, the Court should dismiss Relator's conspiracy claim.

Moreover, Relator does not contest the applicability of the intracorporate conspiracy doctrine, but instead, citing a single case, mistakenly asserts that it should not be applied here. *See* ECF 58 at 22 (citing *United States v. Medoc Health Servs., LLC*, 470 F. Supp. 3d 638, 659 (N.D. Tex. 2020)). First, Relator asserts that the doctrine does not apply because Defendants did not operate within "the same legal structure." *Id.* But *Medoc* holds that if one set of affiliated entities conspire with a *non-affiliated* company, the doctrine does not apply. 470 F. Supp. 3d at 659. Here, by contrast, Relator asserts that Defendants are related through affiliation, common control or employment. *See* ECF 52 ¶¶ 15–61, 254–306; ECF 52-1. Courts routinely hold that the doctrine applies to related entities of the type alleged here.⁵

⁵ See, e.g., Wade v. Jackson Ass'n of Realtors, 615 F. App'x 238, 240 (5th Cir. 2015) (affirming summary judgment where plaintiff alleged conspiracy between association, its subsidiary, association's CEO, and subsidiary's CEO, president and board member, finding "the alleged co-conspirators for both claims are [defendant association], its subsidiary, and its agents, but organizations cannot conspire with their own agents" (citation omitted)); see also Hawaii ex rel. Torricer v. Liberty Dialysis-Hawaii LLC, 512 F. Supp. 3d 1096, 1118 (D. Haw. 2021) ("[T]he conspiracy claims also fail because, at best, the [complaint] alleges that the Defendants are all affiliated with one another" and are "thus barred by the intracorporate conspiracy doctrine"); U.S. ex rel. Rector v. Bon Secours Richmond Health Corp., 2014 U.S. Dist. LEXIS 52161, at *37-38 (E.D. Va., Apr. 14, 2014) ("[T]he named Defendants are legally incapable of conspiring with each other because they are related entities or subsidiaries." (citation omitted)); U.S. ex rel. Head v. Kane & Co., 798 F. Supp. 2d 186, 201 (D.D.C. 2011) (finding company could not have conspired with its employees); U.S. ex rel. DRC, Inc. v. Custer Battles, LLC, 376 F. Supp. 2d 617, 618–19, 651 (E.D. Va. 2005) (dismissing conspiracy allegation against company, three entities alleged to be its subsidiaries or related "through common ownership," and employees of company or related entities, as the fact that "[e]very defendant named in the complaint in addition to [the company] is an employee of [the company], a related entity or a subsidiary . . . or an employee of one of those entities" meant conspiracy was a "legal impossibility" (footnote and citation omitted)), rev'd in part on other grounds, 562 F.3d 295 (4th Cir. 2009).

Additionally, Relator is wrong in contending that the "rare" exception to the doctrine—where the alleged conspirators possess "an independent stake in achieving the object of the conspiracy" and act for their own personal purposes, *H&B Equip. Co. v. Int'l Harvester Co.*, 577 F.2d 239, 244 (5th Cir. 1978)—applies. Relator cites to a single case, *Collins v. Bauer*, in support. In *Collins*, the court found that this rare exception applied because police officers, who allegedly beat a person, violated their employer's policies and acted outside the scope of their employment to advance their personal interests rather than the interests of the police department. 2012 U.S. Dist. LEXIS 17769, at *19–25 (N.D. Tex. Jan. 23, 2012). Here, Relator's FAC pleads the precise opposite—that is, all Defendants acted in concert to achieve a common purpose. *See* ECF 52 ¶¶ 15–61, 254–306.⁶ Accordingly, Relators' FCA conspiracy allegation should be dismissed.

B. Relator's FCA Allegations Fail to Meet Rule 9(b)'s Heightened Pleading Requirements

Defendants pointed out that Relator cannot satisfy Rule 9(b) because Relator does not allege any facts regarding any specific instance in which any Defendant allegedly caused any specific sales representative to exercise unlawful influence over a referral decision of any patient specimen, such as (i) who the Defendant was, (ii) who the sales representative was, (iii) what the unlawful influence over the healthcare decisionmaker's referral decision was, or (iv) who the patient was; hence, he does not allege the "who, what, when, where, and how" of the alleged fraud.

⁶ Relator does not plead in his FAC that Defendants had separate interests in violating the AKS, EKRA and FCA. He cannot use an opposition brief to amend a complaint. *See U.S. ex rel. Hanna v. City of Chi.*, 834 F.3d 775, 779 (7th Cir. 2016) (finding court could not consider assertions set out in briefing but not in pleadings, observing "[f]raud and mistake must be pled with particularity; the pleader is not free to hold back and add facts via affidavit or brief," as the "purpose of Rule 9(b) is to 'force the plaintiff to do more than the usual investigation before filing his complaint" (citation omitted)); *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 460 n.9 (4th Cir. 2013). Accordingly, the Court should reject Relator's contention.

U.S. ex rel. Colquitt v. Abbott Labs., 858 F.3d 365, 371 (5th Cir. 2017).

Relator, in response, states that he complies with Rule 9(b) because the FAC "delineates the roles of the Defendants in this scheme" (citing ECF 52 ¶ 21–22, 26–29, 34, 38–39, 48–50, 55–57, 117, 212–13 as to some Defendants, and citing *id.* ¶¶ 45–47, 59–60, 256–60, 265–67, 301–06 as to other Defendants). ECF 58 at 24. Under Circuit authority, the alleged "scheme" would have to be the improper influence a particular salesperson allegedly exercised over a specific clinician as to the referral of a specimen. None of the paragraphs Relator cites identify (i) a particular sales representative (ii) exercising improper influence (iii) over any specific clinician (iv) that resulted in the referral of a particular specimen (v) that resulted in Apollo billing, on a specific date, a specific false claim for payment to federal health care programs. Indeed, Relator admits that he cannot plead any of these facts because he and Defendants do not know what interactions, if any, occurred between the salespersons and the clinicians. *See* ECF 52 ¶ 159. Accordingly, Relator's FAC should be dismissed under Rule 9(b). *See Integra Med Analytics, L.L.C.*, 816 F. App'x at 900 (holding Rule 9(b) not satisfied when relator alleges a general scheme but does not link to any defendant details of an alleged fraud claim).

III. CONCLUSION

For the foregoing reasons, the Court should dismiss Relator's FCA claims with prejudice.⁷

.

⁷ Although Relator requests an opportunity to yet again amend his FAC upon dismissal, he does not explain how he could remedy the defects in his FAC, and, in his FAC, he admits that neither he nor Defendants possess facts that could remedy what his FAC lacks—namely, that an independent contractor salesperson improperly influenced a gatekeeper clinician's referral decision. See ECF 52 ¶ 159. Moreover, any further amendment would be brought in bad faith because, in this over-four-year-old FCA action, Relator was expected not to withhold relevant facts and to bring all his facts forward so the government could investigate them prior to its intervention decision. See, e.g., U.S. ex rel. Nicholson v. MedCom Carolinas, Inc., 42 F.4th 185, 199 (4th Cir. 2022) (ruling a factor in finding bad faith could include relator waiting, like here, four years to amend a complaint with additional alleged facts). Accordingly, dismissal should be with prejudice.

Date: December 9, 2024 Respectfully submitted,

/s/Elizabeth D. Scott

Elizabeth D. Scott
Texas Bar No. 24059699
AKIN GUMP STRAUSS HAUER & FELD LLP
2300 North Field Street
Suite 1800
Dallas, TX 75201
Telephone: (214) 969-2800

Facsimile: (214) 969-2800 Facsimile: (214) 969-4343 edscott@akingump.com

Robert S. Salcido
D.C. Bar No. 447951
Emily I. Gerry
D.C. Bar No. 1743489
AKIN GUMP STRAUSS HAUER & FELD LLP
2001 K Street N.W.
Washington, DC 20001
Telephone: (202) 887-4095
Facsimile: (202) 877-4288
rsalcido@akingump.com
(admitted pro hac vice)
egerry@akingump.com
(admitted pro hac vice)

Attorneys for Defendants
Apollo Path, LLC D/B/A Apollo
Laboratories; Apollo Laboratories Services,
LLC; Arbor Diagnostics, Inc.; Korenvaes
Management, LLC; David Key; Brian
Oliver; Max Korenvaes

CERTIFICATE OF SERVICE

This is to certify that I, Elizabeth D. Scott, one of the attorneys for Defendants, individually and on behalf of the Defendants, have this day furnished a true and correct copy of the above and foregoing REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE FIRST AMENDED COMPLAINT to the following via ECF filing:

Cory Steven Fein Cory Fein Law Firm 712 Main Street, Suite 800 Houston, TX 77002 cory@coryfeinlaw.com

Christopher R. O'Hara
Evan A. Johnson
Todd & Weld LLP
One Federal Street
Boston, MA 02110
cohara@toddweld.com
ejohnson@toddweld.com

Jeffrey A Newman Newman & Shapiro 1 Story Terrace Marblehead, MA 01945 jeffrey.newman1@gmail.com Seth J. Robbins
Todd & Weld LLP
One Federal St, 27th Fl
Boston, MA 02110
srobbins@toddweld.com

PageID 456

Dawn Whalen Theiss-DOJ US Attorney's Office Northern District 1100 Commerce Street Third Floor Dallas, TX 75242 dawn.theiss@usdoj.gov

This 9th day of December, 2024.

/s/ Elizabeth D. Scott
Elizabeth D. Scott